

COMPARISON OF POLYETHYLENE GLYCOL AND LACTULOSE IN MANAGEMENT OF FUNCTIONAL CONSTIPATION: A RANDOMIZED CONTROLLED TRIAL

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Copyright @Author Corresponding Author: * Hafiz Muhammad Umer Abstract *Objectives:* To compare the Lactulose and Polyethylene Glycol in relieving the functional constipation symptoms in terms of improvement in defecation frequency per week in our study cases.

Study Design: Randomized clinical trial.

Place & Duration of Study: Department of Pediatric Surgery University of Child Health Sciences Children Hospital Lahore (UCHS-CHL) from July 2024 to December 2024.

Materials & Methods: Total ninety (90) patients fulfilling the inclusion criteria of the study were randomized into two (2) groups forty-five (45) each. Group A patients received PEG (0.8g/kg/day) therapy for 8 weeks and Group B patients received Lactulose (2g/kg/day) therapy for 8 weeks. Both groups were compared in terms of improvement in defecation frequency at the end of 8 weeks of therapy. Successful outcomes were considered in patients passing stool 3 or more than 3 times / week at the end of study.*Data were analysed using SPSS version 26. Results:* Both the study groups were comparable with respect to gender & weight distribution. In PEG group male to female ratio was 3.5:1 while it is 2:1 in Lactulose group with P value >0.05. Mean weight in PEG group was 15.4 kg and in Lactulose group it was 12.8 kg with P value > 0.05. Mean defecation frequency / week at pesentation is 1.4 in PEG group and 1.3 in Lactulose group with P value >0.05.

Mean defecation frequency / week at the end of study in PEG group was 8.6+- 2.7 while in Lactulose group it is 5.8 +- 3.0 with P value <0.05. Successful outcomes were recorded to be 93.3 % in PEG group while it is 80 % in Lactulose group with P value > 0.05.

Conclusion: Study found that both PEG & Lactulose are effective in treatment of functional constipation in pediatric age group but the results of PEG are better compared to Lactulose though it is not statistically significant in our study.

INTRODUCTION

Constipation is characterized by infrequent, difficult, painful or incomplete bowel movements, and is often referred to as 'functional constipation' when it is caused by a lack of organic origin with symptoms persisting for more than one month. Constipation accounts for one of the most common problem



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related to gastro-intestinal tract and constitutes of about 3 -5% of all admission related to pediatric medical services as well as it constitutes about 25% of gastrointestinal tract disorders[1]. Children suffering from functional constipation may also experience recurrent episodes of fecal incontinence due to the buildup of feces leading to overflow incontinence. Functional constipation is a common gastrointestinal disorder in children and can have significant implications on a child's health and wellbeing if not properly managed and can lead to development of anal fissure as well. Various factors leading to functional constipation in children include poor water intake, insufficient dietary fiber and stool with holding behavior due to fear of painful defecation. (2,3). The evidence for functional constipation as defined by the ROME IV diagnostic indicators, which were to develop diagnostic criteria for functional constipation disorders in children (4). Diet rich in fiber, education of the parents, medication along with toilet training are all part of the treatment. Osmotic laxatives are indicated as first-line therapy for functional constipation in children. Lactulose and PEG both are laxatives and have different properties and mechanism of action. Lactulose which is a synthetic disaccharide is fermented by intestinal bacteria leading to reduced colonic PH and resultantly increases fecal volume & overall reduction in transit time of colon. Lactulose is commonly prescribed in patients presenting with problem of constipation. Polyethylene glycol (PEG) on the other hand is a non-absorbable, nonmetabolized polymer that acts as a pure osmotic agent. It functions by bringing water into the intestines, where it softens the stool thus enabling simpler bowel movements. (5). Maintaining a healthy weight and drinking enough water can help laxatives work more efficiently. (6).

Many international studies have been carried out to compare the clinical effectiveness of both these drugs. Both the drugs are being used in the treatment of functional constipation with variable results in terms of improvement in defecation frequency per week (6) In our institution, no such study has been carried out to provide evidence-based guidelines in managing patients of pediatric age group with functional constipation. The aim of this study is to compare the effectiveness of PEG and Lactulose in relieving functional constipation in the children (1 year to 12 years) in our university teaching hospital. This will provide us evidence-based data of both these drugs efficacy in our study population in relieving functional constipation symptoms which is very common problem in pediatric age group and to opt a better management plan.

Materials & Methods:

This randomized controlled trial was conducted at the Department of Pediatric Surgery, University of Chiild Health Sciences, Children Hospital Lahore (UCHS-CHL) from July 2024 to December 2024. Study was approved by institutional review board (IRB) of University of Child Health Sciences Children Hospital Lahore (UCHS-CHL). Written and informed consent was taken from legal guardians of all children before including them in study.

The sample size was calculated (power of study 80 %,5% level of significance) using success rate of 95% in PEG group and 77% in Lactulose. The calculated sample was 90, 45 in each group. Total ninety (90) patients falling in age 1 to 12 years fulfilling the inclusion criteria of the study were registered and randomized into two (2) groups forty five (45) each using lottery method with allocation ratio 1:1. Group A patients received PEG (0.8g/kg/day) therapy and Group B patients received Lactulose (2g/kg/day) therapy in two divided doses for 8 weeks. Both groups were compared in terms of improvement in defecation frequency at the end of 8 weeks of therapy. Successful outcomes were labelled to patients in each group with 3 or more than 3 times defecation per week at the end of 8 week of treatment. Rome IV criteria for functional constipation in children serve as diagnostic guidelines. Data on demography, clinical profile and outcome variables were recorded on a predesigned Performa.

Statistical Analysis:

All the data will be analyzed by using SPSS version 26. The data will be analyzed into two variables such as quantitative and qualitative. The quantitative variables like age, weight, defection frequency will be presented as Mean +_ S.D and qualitative variables

like gender and improved outcomes will be analyzed by percentages and frequency. Improvement will be compared in both groups using chi – square test. Data will be stratified for age, gender and weight. Post stratification chi square test will be applied. P value equal or less than 0.05 will be considered statistically significant. The results of data will be presented in the form of tables and graphs.

Results:

In our study total 90 patients were included, 45 in each group after randomization with allocation ratio 1:1. Maximum age (Years) recorded in our data was 11 years while minimum age was 1.3 years with mean value 4.4 years. Mean age in years in the PEG group was 5.0 with S.D 3.1 while in the Lactulose group it is 3.8 with S.D 2.5 and P value came out to be 0.039 (<0.05) as shown in table 1.

Out of 90 patients total males were 65 and females were 25. In the PEG group out of 45 patients male patients were 35 while female patients were 10 with ratio (3.5:1) while in lactulose group male patients were 30 and female patients were 15 having ratio (2:1) with P value 0.239 (>0.05) which is shown in table 1.

Maximum weight (kg) in our study cases recorded was 32 kg while minimum weight was 6.7 kg with mean weight 14.1 kg. Mean weight in the PEG group came out to be 15.4 kg with S.D 6.9 while it is 12.8 kg with S.D 5.1 with P value 0.417 (>0.05) which



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means both groups were comparable in terms of weight and gender (Table 1).

At presentation mean defecation frequency / week in our study cases was found to be 1.35. In PEG group it was 1.4 per week with S.D 0.4 while in Lactulose group it was 1.3 per week with S.D 0.4 with P value 0.071 (> 0.05) which means both groups were comparable in terms of defecation frequency at presentation as shown in (Table 2).

Mean defecation frequency at the end of study (8th Week) in PEG group came out to be 8.6 with S.D. 2.7 while in Lactulose group it was 5.6 with S.D 3.0 with P value 0.0001 (<0.05) which means statistically significant improvement observed in both groups as shown in table 2. Successful outcomes were recorded in 93.3 % in PEG group in which 42 patients out of 45 responded well to treatment while in Lactulose group it came out be 80.0 % which means 36 patients out of 45 responded well to treatment with P value 0.063 (> 0.05) which came out to be statistically non-significant and the results are shown in graph 1. Results showing that there is significant improvement in both groups and in comparison PEG group showed more improvement than Lactulose but it was statistically non-significant with P value 0.063 (> 0.05) as shown in graph.

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Variables	PEG Group	Lactulose Group	P-value
Mean Age (Years)	5.0 +- 3.1	3.8 +- 2.5	0.039
Gender (M : F)	(3.5:1)	(2:1)	0.239
Mean Weight (kg)	154 + 69	128+51	0.417

Table 1. Comparison of Demographic Variables in both Groups



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 Table 2. Comparison of Outcome Variables in both Groups

Variables	PEG Group	Lactulose Group	P Value
Mean Defecation frequency / week at presentation	1.4 +- 0.4	1.3 +- 0.4	0.071
Mean Defecation frequency / week at the end of study	8.6 +- 2.7	5.6 +- 3.0	0.0001

Discussion:

In pediatric patients of chronic constipation, functional constipation constitutes about 90 to 95% of it [7]. Pathophysiology of functional constipation is not fully understood uptill now and likely it is multifactorial in origin [8]. Among the significant underlying reason of constipation in pediatric age group is stool withholding behavior which develops due to difficult and painful bowel movements [8]. Fecal incontinence can be produced by retained fecal mass in rectum leading to multiple visits in hospital due to involuntary evacuation of bowel. Lactulose is not digested in gastrointestinal tract & because of its osmotic effects if softens the feces, facilitates the formation of gas by intestinal bacteria decrease PH of the stool & exacerbates intestinal peristalsis. [8] While Polyethylene glycol is an osmotic laxative agent which is absorbed in trace amounts only from the gastrointestinal tract and routinely used to treat chronic constipation.[7]

This randomized controlled trial evaluated the effectiveness of PEG and lactulose in managing functional constipation in terms of stool frequency per week. Effect of both the medications was compared by observing stool frequency at presentation and starting with drug therapy after 8 weeks of application. Both groups are comparable in terms of weight and gender distribution.

Stool frequency in both the groups was 1-2 per week before application of any medication (p-value 0.07). PEG given after dis-impaction to patient at dose of 0.8 g / kg / day in two equally divided doses for 8 weeks and Lactulose given at dose of 2 g / kg / day in two equally divided doses for 8 consecutive weeks to the selected groups respectively and post applications results were compared. Mean stool frequency in PEG group came out to be 8.6 ± 2.7 per week while in lactulose group, it was 5.6 ± 3.0 per week (p-value 0.0001). In our study, PEG showed better results in terms of improvement in frequency of stool per week as compared to lactulose.

Multiple studies compared the results of PEG and lactulose in management of functional or chronic constipation. Meryem Keçeli Başaran described results similar to our study and described that patients receiving PEG had better outcome with respect to number of daily bowel movement and pain during bowel movement as compared to lactulose.[8] Wang et al [9] also described that PEG improved frequency of stool per week from 2 to 7 and is better in managing constipation than lactulose. Similarly, Voskuijl et al [10], Rendeli et al [11] and Saneian and Mostofizadeh [12] supported our finding of better results with PEG in improving frequency of stool per week than lactulose.

In 2002, Gremse et al.[13] conducted similar research. According to him, there was no statistical

difference between two groups with respect to the number of stool frequency per week. Dupont et al. (14) also could not establish any statistical difference between the two groups.

An important aspect of management of functional constipation is the stoppage of medication. Abrupt and sudden stoppage of medication leads to recurrence of symptoms. Hanin described in his study an increased ratio of relapses in patients of functional constipations who had stopped receiving therapy abruptly without tapering the dose and it was found significantly higher comparatively in lactulose group. Early and immediate stoppage of medication should be avoided as it has an important part in developing recurrence of the problem.[15]

In line with our findings, the ESPGHAN and NASPGHAN guidelines recently recommended Polythylene Glycol 3350 as the main treatment for children with constipation. If PEG is not available, lactulose may be administered [16].

Limitation:

Single center study. Multicenter studies with large study population are needed for generalization and more acceptable results.

Conclusion:

Our study found that both Lactulose & PEG are effective in treatment of functional constipation in pediatric age group in terms of improvement in defecation frequency / week but the results of PEG are better compared to Lactulose though it is not statistically significant in our study but we should opt it for treating patients with functional constipation which takes long time to treat and is always a dilemma to deal with.

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